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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Introduction

As part of Registration Review, the Pesticide-Reevaluation Division (PRD) of OPP has requested that the Health Effects Division (HED) conduct an occupational and residential exposure assessment, as needed, to estimate the risk to human health that will result from the currently registered use of propanil.

It is HED policy to use the best available data to assess exposure. Several sources of generic data were used in this assessment as surrogate data in the absence of chemical-specific data, including the Pesticide Handlers Exposure Database Version 1.1 (PHED 1.1) and the Outdoor Residential Exposure Task Force (ORETF) database, the Agricultural Handler Exposure Task Force (AHETF) database and the Residential Standard Operating Procedures (SOPs). Some of these data are proprietary, and subject to the data protection provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Note: This memorandum was reviewed by the Exposure Science Advisory Committee (ExpoSAC) on June 6, 2019.

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1.0 Executive Summary

Propanil *N*-(3,4-dichlorophenyl) propanamide is a selective postemergence herbicide registered for use on rice to control broadleaf and grass weeds. Propanil belongs to the acetanilide class of pesticides and, acting primarily in the leaves, is a strong inhibitor of the *Hill reaction,* disrupting normal photosynthesis.

Use Profile

Propanil has numerous end-use products that are registered for use on rice. There are no currently registered residential uses for propanil. Propanil is marketed as emulsifiable concentrate (EC), dry flowable (DF) and soluable concentrate (SC) formulations and may be applied by aerial and groundboom equipments only. Propanil products are used for postemergence control of broadleaf and grass weeds in rice fields. The use of chemigation equipment and human flaggers are prohibited on all registered products. Products registered for propanil are applied at a maximum application rate of 6.0 lb ai/A. In terms of personal protective equipment (PPE), the propanil labels require handlers to wear baseline attire (i.e., long-sleeved shirt, long pants, shoes and socks), eyewear, coveralls and chemical-resistant gloves. The restricted entry interval (REI) listed on all registered labels is 24 hrs.

Exposure Profile

Based on the currently registered use of propanil, the durations of exposure are expected to be both short- (1 to 30 days) and intermediate-term (1 to 6 months) for agricultural occupational handlers and post-application workers. Residential exposures are not expected because there are no registered or proposed residential uses associated with propanil. Exposures from non-occupational spray drift are expected to be short-term only.

Hazard Characterization

No systemic effects were seen in the available subchronic dermal toxicity study in rabbits up to the limit dose, and a susceptibility issue of concern was not identified in the young in the developmental toxicity studies in rats and rabbits or the multigeneration reproduction study in rat. As a result, a dermal point of departure, POD was not selected. Short- and intermediate- term incidental oral was based on the LOAEL of 9.0 mg/kg/day (methemoglobinemia) from the chronic toxicity/carcinogenicity study in rats. For occupational exposures, the uncertainty factor was 300X (10X for interspecies extrapolation, 10X for intraspecies variability and 3X for LOAEL-to-NOAEL extrapolation). A route-specific subchronic inhalation study is available and was used to set the POD for inhalation exposures, which is the no observed adverse effect concentration, NOAEC of 0.393 mg/L. The lowest observed adverse effect concentration, LOAEC of 0.893 mg/L is based on hematology changes and corroborating histopathology in spleen and bone marrow and increased spleen weights in male and female rats. The uncertainty factor was 30X (3X for interspecies extrapolation (Human Equivalent Doses calculated) and 10X for intraspecies variability). Inhalation absorption assumed to be 100% of oral absorption. A 1X FQPA SF was considered appropriate because the toxicology database was adequate for assessing FQPA, a developmental neurotoxicity study was not required for this chemical and there was no evidence of increased quantitative susceptibility of the young following *in utero*, pre- or post-natal exposure to propanil.

Residential Exposure and Risk Estimates

There are no proposed or registered residential uses for propanil. Therefore, residential handler and post-application exposure and risks were not assessed.

Non-Occupational Exposure – Spray Drift Assessment

Since no hazard was identified for the dermal route of exposure, dermal risks were not assessed for adults or children (1 to <2 years old). Incidental oral risk estimates for children (1 to <2 years old) were evaluated. For children (1 to <2 years old) incidental oral MOEs at the edge of the field ranged from 380 to 530 (level of concern [LOC] = 300); therefore, there are no risks of concern at the field edge for either groundboom or aerial applications.

Occupational Handler Exposures and Risk Estimates

Since no hazard was identified for the dermal route of exposure, dermal risks were not assessed. All inhalation exposures result in short- and intermediate-term MOEs ranging from 120 to 210,000 with baseline attire (i.e, no respirator) and are not of concern to HED (i.e. MOE $\geq$ 30).

Occupational Post-Application Exposures and Risk Estimates

Occupational short- and intermediate-term dermal exposures are expected from post-application activities. However, since no hazard was identified for the dermal route of exposure, dermal risks were not assessed.

Based on the Agency's current practices, a quantitative non-cancer occupational post-application inhalation exposure assessment was not performed for propanil at this time. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for propanil.

Restricted Entry Interval (REI)

Propanil has low acute toxicity, with toxicity categories of III (oral) and IV (dermal, inhalation and primary skin irritation). Dermal sensitization was observed in the Local Lymph Node Assay (LLNA); however, primary eye irritation is observed in rabbits (toxicity category II). Therefore, the Worker Protection Standard (WPS) REI of 24 hours on the registered label is adequate to protect agricultural workers from post-application exposures to propanil.

Human Studies Review

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from PHED 1.1, Residential SOP and the AHETF database; are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency website[1].

[1] http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data and http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-post-application-exposure

2.0 Risk Assessment Conclusions and Recommendations

There are no occupational risk estimates of concern associated with the registered use of propanil. There are no non-occupational spray drift risk estimates of concern for children 1 to <2 years old associated with the registered use of propanil.

2.1 Summary of Risk Estimates

The occupational handler inhalation exposure and risk estimates are not of concern to HED for all scenarios assuming the use of baseline PPE (i.e, no respirator). The MOEs range from 120 to 210,000 (inhalation LOC = 30).

Since no hazard was identified for the dermal route of exposure, dermal risks were not assessed for adult and children (1 to <2 years old). For spray drift, incidental oral risk estimates for children (1 to <2 years old) were evaluated; MOEs at the edge of the field ranged from 383 to 527 (LOC = 300).

2.2 Label Recommendations from Occupational Assessment

There are no label recommendations based on the exposure and risk assessment for the registered use on rice.

2.3 Data Deficiencies and Requirements

None.

3.0 Hazard Characterization

Acute Toxicity

Propanil has low acute toxicity, with toxicity categories of III (oral) and IV (dermal, inhalation and primary skin irritation). Dermal sensitization was observed in the Local Lymph Node Assay (LLNA); however, primary eye irritation is observed in rabbits (toxicity category II). Table 3.1 presents a summary of the acute toxicity information for propanil.

Table 3.1. Acute Toxicity profile of Propanil

Guideline No.	Study Type	MRID #	Results	Toxicity Category
870.1100	Acute Oral Toxicity – rat	44751502[1]	LD_{50} = 779 mg/kg (M) LD_{50} = 907 mg/kg (F) LD_{50} = 841 mg/kg (C)	III
870.1200	Acute Dermal Toxicity - rat	44685901[1]	LD_{50} > 5000 mg/kg (M and F)	IV
870.1300	Acute Inhalation Toxicity – rat	44685902[1]	LC_{50} > 2.13 mg/L (M and F)	IV
870.2400	Acute Eye Irritation - rabbit	41360501[2]	Iritis, conjunctivitis present in all rabbits, cleared by day 14; corneal opacity cleared by 4 days	II
870.2500	Acute Dermal Irritation - rabbit	44751504[1]	Not Irritating	IV
870.2600	Skin Sensitization -guinea pig (Buehler)	44751505[1]	Negative for dermal sensitization	NA

Table 3.1. Acute Toxicity profile of Propanil				
Guideline No.	**Study Type**	**MRID #**	**Results**	**Toxicity Category**
	Skin Sensitization -mice (LLNA)	49566801[3]	Positive for dermal sensitization	NA

[1] TXR 5002257 (D253646, E. McAndrew, 04/22/1999) – Test material – 97.5%
[2] TXR 0008430 (W. Dykstra, 07/02/1991) – Test material – 100%
[3] TXR 5015563 (D426812, E. McAndrew, 06/03/2015) – Test material – 98.9%

Toxicological PODs Used for Risk Assessment

No systemic effects were seen in the available subchronic dermal toxicity study in rabbits up to the limit dose, and a susceptibility issue of concern was not identified in the young in the developmental toxicity studies in rats and rabbits or the multigeneration reproduction study in rat. As a result, a dermal POD was not selected. A route-specific subchronic inhalation study is available and was used to set the POD for inhalation exposures, which is the NOAEC of 0.393 mg/L. The LOAEC of 0.893 mg/L is based on hematology changes and corroborating histopathology in spleen and bone marrow and increased spleen weights in male and female rats. The uncertainty factor was 30X (3X for interspecies extrapolation (Human Equivalent Doses calculated) and 10X for intraspecies variability). Short- and intermediate- term incidental oral was based on the LOAEL of 9.0 mg/kg/day (methemoglobinemia) from the chronic toxicity/carcinogenicity study in rats. For occupational exposures, the uncertainty factor was 300X (10X for interspecies extrapolation, 10X for intraspecies variability and 3X for LOAEL-to-NOAEL extrapolation).

Inhalation absorption assumed to be 100% of oral absorption. A 1X FQPA SF was considered appropriate because the toxicology database was adequate for assessing FQPA, a developmental neurotoxicity study was not required for this chemical and there was no evidence of increased quantitative susceptibility of the young following *in utero*, pre- or post-natal exposure to propanil.

The endpoint selections for propanil are summarized in Table 3.2 as follows.

Table 3.2. Summary of Toxicological Doses and Endpoints for Propanil for Use in Occupational and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure (PoD)**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Incidental oral Short-term and intermediate term	LOAEL = 9.0 mg/kg/day	UF_A = 10x UF_H = 10x UF_L = 3x	LOC for MOE = 300	Chronic toxicity/carcinogenicity study in rats (MRID 43303201) Increased methemoglobin in both sexes, increased spleen weight in females and small seminal vesicles/prostate in males
Dermal Short-term and intermediate-term	A dermal risk assessment is not required because no effects were seen in the 21-day dermal study up to the limit dose (1000 mg/kg/day) and no susceptibility was identified in the database.			

Table 3.2. Summary of Toxicological Doses and Endpoints for Propanil for Use in Occupational and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure (PoD)**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Inhalation[b] Short-term and intermediate-term	LOAEL = 0.393 mg/L HED $_{Handler}$ = 94.64 mg/kg/day HEC $_{Handler}$ = 1.00 mg/L	UF_A = 3x UF_H = 10x	LOC for MOE = 30	Subchronic inhalation study – rats (MRID 50294601) LOAEC = 0.823 mg/L based on changes in hematology parameters and corroborating histopathology in spleen and bone marrow, and increased spleen weights, in both sexes.
Cancer (oral, dermal, inhalation)	Classification: "Suggestive evidence of carcinogenic potential by all routes of exposure, but not sufficient to assess human carcinogenic potential".			

Point of departure (PoD) = a data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = interspecies extrapolation. UF_H = intraspecies variability. UF_L = LOAEL-to-NOAEL extrapolation. FQPA SF = FQPA Safety Factor. LOC = level of concern.

Table 3.3 contains HECs and HEDs for potential occupational scenarios.

Table 3.3 Summary of HEC/HED values for Propanil from the 90-day Inhalation Rat Study						
Population	**Scenario**	**Tox duration adjustment**		**HEC**		**HED (mg/kg-day)**
		Daily	**Weekly**	**mg/L**	**mg/m3**	
Occupational	Handler	0.75	1	1.000	1000.087	94.637
Residential	Handler	NA	NA	1.333	1333.449	31.546
	Outdoor post-application	NA	NA	1.333	1333.449	36.277
	Indoor Post-application	NA	0.71428571	0.952	952.464	22.533
	Bystander	0.25	0.71428571	0.238	238.116	NA

Regional Deposited Dose Ratios (RDDR) value of 3.393 was calculated from the mean MMAD of 2.77 and mean GSD of 1.62 at the NOAEC in the 28-day inhalation study in rats (MRID 50294601). Body weight of 182 gm was determined by averaging female body weights at day 0 and day 28. In the inhalation study, the POD was the NOAEC of 0.393 mg/L following exposure 6 hr/day, 5 day/wk for four week. These values, along with the RDDR were used to calculate the results seen in the above table.

Body Weight

The standard body weight for the general population (80 kg) was used for all adult exposure scenarios covered in this risk assessment since the endpoints selected were not based on developmental and/or fetal effects. A body weight of 11 kg was used to assess child (1 to <2 years old) exposure to spray drift.

4.0 Use Profile

Propanil has several end-use products that are registered for use on rice only. Propanil is marketed as emulsifiable concentrate (EC), dry flowable (DF) and soluble concentrate (SC) formulations and may be applied by aerial or groundboom equipment only (chemigation and the use of human flagging are prohibited on the registered labels). Propanil products are used for postemergence control of broadleaf and grass weeds in rice fields. In terms of PPE, the

propanil labels require handlers to wear baseline attire (i.e., long-sleeved shirt, long pants, shoes and socks), protective eyewear and chemical-resistant gloves and coveralls. Table 4.1 provides a summary of the registered use for propanil. The REI listed on all registered labels is 24 hrs.

Table 4.1. Summary of Directions for Use of Propanil.

Formulation Type	Type of Application	EPA Reg. No.	Maximum Single Application Rate	Application Equipment	PPE	REI hrs	Use Directions and Limitations
RICE							
Dry Flowable (DF)	Broadcast	71085-23, 71085-32, 71085-38, 86363-19, 71085-22, 71085-32, 71085-6, 87290-17, 71085-16	6 lb ai/A	Aerial, Groundboom	• Chem. resistant gloves • Coveralls • Chem. resistant headgear • Long-sleeve shirt, long pants, shoes/socks • Protective eyewear	24	Human flagging is not permitted. Do not apply through any type of irrigation system. Do not apply this product within 60 days of harvest.
Emulsifiable Concentrate (EC)	Broadcast	71085-9, 71085-2, 71085-20 71085-25, 71085-26, 71085-29 71085-3, 71085-30, 71085-31 71085-36, 71085-9, 87290-32, 71085-5	6 lb ai/A	Aerial, Groundboom	• Chem. resistant gloves • Coveralls • Chem. resistant headgear • Long-sleeve shirt, long pants, shoes/socks • Protective eyewear	24	71085-26 (ground only). Human flagging is not permitted. Do not apply through any type of irrigation system. Do not apply this product within 60 days of harvest.
Soluble Concentrate (SC)	Broadcast	87290-18, 19713-576, 71085-39	6 lb ai/A	Aerial, Groundboom	• Chem. resistant gloves • Coveralls • Chem. resistant headgear • Long-sleeve shirt, long pants, shoes/socks Protective eyewear	24	Human flagging is not permitted. Do not apply through any type of irrigation system. Do not apply this product within 60 days of harvest.

5.0 Residential Exposure and Risk Estimates

There are no registered residential uses for propanil. Therefore, residential handler and post-application exposures/risks were not assessed.

6.0 Non-Occupational Spray Drift Exposure and Risk Estimates

Off-target movement of pesticides can occur via many types of pathways and it is governed by a variety of factors. Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact. They can also deposit on surfaces where contact with residues can eventually lead to indirect exposures (*e.g.*, children

playing on lawns where residues have deposited next to treated fields). The potential risk estimates from these residues can be calculated using drift modeling onto 50 feet wide lawns coupled with methods employed for residential risk assessments for turf products.

The approach to be used for quantitatively incorporating spray drift into risk assessment is based on a premise of compliant applications which, by definition, should not result in direct exposures to individuals because of existing label language and other regulatory requirements intended to prevent them.[2] Direct exposures would include inhalation of the spray plume or being sprayed directly. Rather, the exposures addressed here are thought to occur indirectly through contact with impacted areas, such as residential lawns, when compliant applications are conducted. Given this premise, exposures for children (1 to 2 years old) and adults who have contact with turf where residues are assumed to have deposited via spray drift thus resulting in an indirect exposure are the focus of this analysis analogous to how exposures to turf products are considered in risk assessment.

In order to evaluate the drift potential and associated risks, an approach based on drift modeling coupled with techniques used to evaluate residential uses of pesticides was utilized. Essentially, a residential turf assessment based on exposure to deposited residues has been completed to address drift from the agricultural applications of propanil**.** In the spray drift scenario, the deposited residue value was determined based on the amount of spray drift that may occur at varying distances from the edge of the treated field using the AgDrift (v2.1.1) model and the *Residential Exposure Assessment Standard Operating Procedures Addenda 1: Consideration of Spray Drift Policy*. Once the deposited residue values were determined, the remainder of the spray drift assessment was based on the algorithms and input values specified in the recently revised (2012) *Standard Operating Procedures For Residential Risk Assessment (SOPs)*.

A screening approach was developed based on the use of the AgDrift model in situations where specific label guidance that defines application parameters is not available.[3] AgDrift is appropriate for use only when applications are made by aircraft, airblast orchard sprayers, and groundboom sprayers. When AgDrift was developed, a series of screening values (i.e., the Tier 1 option) were incorporated into the model and represent each equipment type and use under varied conditions. The screening options specifically recommended in this methodology were selected because they are plausible and represent a reasonable upper bound level of drift for common application methods in agriculture. These screening options are consistent with how spray drift is considered in a number of ecological risk assessments and in the process used to develop drinking water concentrations used for risk assessment. In all cases, each scenario is to be evaluated unless it is not plausible based on the anticipated use pattern (e.g., herbicides are not typically applied to tree canopies) or specific label prohibitions (e.g., aerial applications are not allowed). Table 6.1.1 provides the screening level drift related risk estimates.

6.1 Risk Estimates from Lawn Deposition Adjacent to Applications

The spray drift risk estimates are based on an estimated deposited residue concentration as a result of the screening level agricultural application scenarios. Propanil is used on rice and can

[2] This approach is consistent with the requirements of the EPA's Worker Protection Standard.
[3] http://www.agdrift.com/

be applied via groundboom and aerial equipments. The spray drift assessment was conducted using the highest registered application rate of 6.0 lb ai/acre for use on rice for ground and aerial application. The recommended drift scenario screening level options are listed below:

- **Groundboom applications** are based on the AgDrift® option for high boom height and using very fine to fine spray type using the 90th percentile results.
- **Aerial applications** are based on the use of AgDrift® Tier 1 aerial option for a fine to medium spray type and a series of other parameters, which will be described in more detail below (e.g., wind vector assumed to be 10 mph in a downwind direction for entire application/drift event).

In addition to the screening level spray drift scenarios described above, additional results are provided which represent viable drift reduction technologies (DRTs) that represent potential risk management options (Appendix B, Tables B1 to B4). In particular, different spray qualities have been considered as well as the impact of other application conditions (e.g., boom height, use of a helicopter instead of fixed wing aircraft, crop canopy conditions).

Since no hazard was identified for the dermal route of exposure, dermal risks were not assessed for adults and children (1 to <2 years old). Incidental oral risk estimates for children (1 to <2 years old) was evaluated.

The applicable LOC is 300, so MOEs <300 would be of concern. Children's (1 to <2 years old) incidental oral risk estimates from exposure to propanil related to spray drift result in no risks of concern at the field edge for either groundboom or aerial applications. Results are presented in Table 6.1.1. below.

Table 6.1.1. Children (1 to <2 years old) Risk Estimates (MOEs) Related to Indirect Exposure to Spray Drift for propanil for Incidental Oral Route of Exposure

Crop	Application rate (lb ai/A)	Distance from Field Edge	Incidental Oral MOEs[2]	
			LOC = 300	
		(Feet)	Aerial	Groundboom
Rice	6.0	0	380	530

[1] Risk estimates presented assuming screening-level droplet sizes (fine to medium for aerial applications; very fine to fine for groundboom applications),
[2] Algorithms, assumptions, and calculations for the non-occupational spray drift assessment are provided in Appendix B.

7.0 Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Estimates

Volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0687-0037). The agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0687-0037).

During Registration Review, the agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis are required for propanil.

8.0 Occupational Exposure and Risk Estimates

8.1 Occupational Handler Exposure/Risk Estimates

HED uses the term handlers to describe those individuals who are involved in the pesticide application process. HED believes that there are distinct job functions or tasks related to applications and exposures can vary depending on the specifics of each task. Job requirements (amount of chemical used in each application), the kinds of equipment used, the target being treated, and the level of protection used by a handler can cause exposure levels to differ in a manner specific to each application event.

Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used, occupational handler exposure is expected from the registered agricultural use. The quantitative exposure/risk assessment developed for occupational handlers is based on several scenarios which include mixing/loading/applying liquid and dry flowable formulation of propanil. Refer to Table 8.1.1 for a detailed list of each scenario.

Occupational Handler Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments. Each assumption and factor are detailed below on an individual basis.

Application Rate: Refer to the currently registered use pattern in Table 4.1.

Unit Exposures: It is the policy of HED to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include PHED 1.1, the AHETF database, the, or other registrant-submitted occupational exposure studies. Some of these data are proprietary (e.g., AHETF data), and subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as "unit exposures", are outlined in the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table[4]", which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at the Agency website[5].

Area Treated or Amount Handled: The area treated handled is based on HED ExpoSAC Policy No. 9.1. Refer to Table 8.1.1 for these assumptions for each scenario.

Exposure Duration: HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. Exposure duration is determined by many things, including the exposed population, the use site, the pest pressure triggering the use of the

[4] Available: http://www2.epa.gov/sites/production/files/2015-09/documents/handler-exposure-table-2015.pdf
[5] Available: http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data

pesticide, and the cultural practices surrounding that use site. For most agricultural uses, it is reasonable to believe that occupational handlers will not apply the same chemical every day for more than a one-month time frame; however, there may be a large agribusiness and/or commercial applicators who may apply a product over a period of weeks (e.g., completing multiple applications for multiple clients within a region). For propanil, based on the registered use, short- and intermediate-term exposures are expected.

Mitigation/Personal Protective Equipment - Results are presented for "baseline," defined as a single layer of clothing consisting of a long-sleeved shirt, long pants, shoes plus socks and baseline with protective gloves, and no respirator.

Occupational Handler Non-Cancer Exposure and Risk Estimate Equations

The algorithms used to estimate non-cancer exposure and dose for occupational handlers can be found in Appendix A.

Summary of Occupational Handler Non-Cancer Exposure and Risk Estimates

The occupational handler exposure and risk estimates indicate that the short- and intermediate-term occupational and inhalation MOEs are greater than the level of concern (i.e., MOEs ≥ 30) baseline attire (no respirator). The MOEs range from 120 to 210,000. The summary of the occupational handler exposure and risk estimates are provided in Table 8.1.1.

HED has no data to assess exposures to pilots using open cockpits. The only data available is for exposure to pilots in enclosed cockpits. Therefore, risks to pilots are assessed using the engineering control (enclosed cockpits) and baseline attire (long-sleeve shirt, long pants, shoes, and socks); per the Agency's Worker Protection Standard stipulations for engineering controls, pilots are not required to wear protective gloves for the duration of the application. With this level of protection, there are no risk estimates of concern for applicators.

Table 8.1.1. Occupational Short- and Intermediate-term Handler Inhalation Exposure and Risk Estimates for Propanil.

Exposure Scenario	Crop or Target[1]	Baseline Inhalation Unit Exposure (unless otherwise noted)[2]	Maximum Application Rate[3]	Area Treated or Amount Handled Daily[4]	Inhalation	
					Dose[5]	MOE[6]
		µg/lb ai	*lb ai/A*	*Acres*	*mg/kg/day*	*LOC = 30*
Mixer/Loader						
Mixing/Loading dry flowable for Aerial Application	High acreage field crops (Rice)	8.96	6.0	1200 A	0.806	120
Mixing/Loading dry flowable for Groundboom Application				200 A	0.135	700
Mixing/Loading Liquids for Aerial Application		0.219		1200A	0.0198	4,800
Mixing/Loading Liquids for Groundboom Application				200A	0.00329	29,000
Applicator						
Applying Sprays for Aerial Application	High acreage field crops (Rice)	0.0049 (EC)	6.0	1200 A	0.000441	210,000
Applying Sprays for Groundboom Application		0.34		200 A	0.0051	19,000

1 "High acreage field crops" Rice

2 Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table"; Level of mitigation = Baseline except for aerial applicator which includes engineering controls (EC).

3 Based on the maximum application rates. See Table 4.1.

4 Exposure Science Advisory Council Policy #9.1.
5 Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre) × Area Treated or Amount Handled Daily (A/day) ÷ BW (80 kg).
6 Short- and Intermediate-term Inhalation MOE = Inhalation HED (94.64 mg/kg/day) ÷ Inhalation Dose (mg/kg/day)

8.2 Occupational Post-application Exposure/Risk Estimates

Occupational Post-application Dermal Exposure/Risk Estimates
There is a possibility for agricultural workers to have post-application dermal exposure to propanil following its registered use on rice. However, a dermal hazard was not identified; therefore, a post-application dermal exposure assessment was not conducted.

8.2.1 Occupational Post-application Inhalation Exposure/Risk Estimates

There are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0687-0037). The agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0687-0037). During Registration Review, the agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for propanil.

In addition, the Agency is continuing to evaluate the available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. Given these two efforts, the Agency will continue to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the agency's risk assessments.

Although a quantitative occupational post-application inhalation exposure assessment was not performed, an inhalation exposure assessment was performed for occupational/commercial handlers. Handler exposure resulting from application of pesticides outdoors is likely to result in higher exposure than post-application exposure. Therefore, it is expected that these handler inhalation exposure estimates would be protective of most occupational post-application inhalation exposure scenarios.

Restricted Entry Interval
The REI specified on the registered labels is based on the acute toxicity of propanil. Propanil is classified as Toxicity Category IV via the dermal route and Toxicity Category IV for skin irritation potential. It is not a skin sensitizer. It is classified as Toxicity Category II via eye irritation. Under 40 CFR 156.208 (c) (2) (iii), ai's classified as Acute Category II eye irritation is assigned a 24-hour REI. Therefore, the [156 subpart K] WPS interim REI of 24 hours is adequate to protect agricultural workers from post-application exposures to propanil.

Appendix A. Summary of Occupational Non-cancer Algorithms

Occupational Non-cancer Handler Algorithms

Potential daily exposures for occupational handlers are calculated using the following formulas:

$$E = UE * AR * A * 0.001\ mg/ug$$

where:

E	=	exposure (mg ai/day),
UE	=	unit exposure (µg ai/lb ai),
AR	=	maximum application rate according to registered labels (lb ai A or lb ai/gal), and
A	=	area treated or amount handled (e.g., A/day, gal/day).

The daily doses are calculated using the following formula:

$$ADD = \frac{E * AF}{BW}$$

where:

ADD	=	average daily dose absorbed in a given scenario (mg ai/kg/day),
E	=	exposure (mg ai/day),
AF	=	absorption factor (inhalation), and
BW	=	body weight (kg).

Margin of Exposure: Non-cancer risk estimates for each application handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the toxicological endpoint to the daily dose of concern. The daily d inhalation dose received by occupational handlers are compared to the appropriate POD (i.e., NOAEL) to assess the risk to occupational handlers for each exposure route. All MOE values are calculated using the following formula:

$$MOE = \frac{POD}{ADD}$$

where:

MOE	=	margin of exposure: value used by HED to represent risk estimates (unitless),
POD	=	point of departure (mg/kg/day), and
ADD	=	average daily dose absorbed in a given scenario (mg ai/kg/day).

Appendix B. Summary of Spray Drift Algorithms

Modified TTR Equation to Account for Spray Drift

The equation presented below, should be used to evaluate potential risks from spray drift. This equation is similar to the standard TTR equation, except that an additional term has been included (DF or Drift Fraction) that provides an adjustment for the amount of drift that moves into and deposits in a non-target area, such as a lawn. This equation applies to situations where TTR data are not available.

$$TTR = AR * DF * F * (1\text{-}D)^{t} * CF2 * CF3$$

where:

TTR	=	turf transferable residue ($\mu g/cm^2$)
DF	=	drift fraction of spray drift that deposits on lawns (unitless)
AR	=	application rate (lbs ai/ft^2 or lb ai/acre)
F	=	fraction of ai as transferable residue following application (unitless)
D	=	fraction of residue that dissipates daily (unitless)
T	=	post-application day on which exposure is being assessed (Day 0 in this SOP)
CF2	=	weight unit conversion factor (4.54×10^8 µg/lb)
CF3	=	area unit conversion factor (1.08×10^{-3} ft^2/cm^2 or 2.47×10^{-8} acre/cm^2)

If chemical specific TTR data are available, the residue on Day 0 is used after it is adjusted based on the ratio of the applicable application rate for risk assessment (i.e., based on the crop of concern) and the application rate for the TTR study followed by an additional adjustment for the drift fraction factor as illustrated above.

Drift Fraction Values

The spray drift fraction (DF) values for selected aerial and groundboom application scenarios, based on average deposition values at each distance of interest, are shown in the tables below (Tables B-1 and B-2).

Table B-1. Average Drift Fractions for a 50' Wide Lawn Starting at Various Distances Downwind from a Field Treated Using Aerial Equipment.

Droplet Size+	Distance Downwind from Treated Field (feet)										
	0	10	25	50	75	100	125	150	200	250	300
Fine to Medium*	**0.257**	**0.209**	**0.169**	**0.129**	**0.098**	**0.076**	**0.063**	**0.054**	**0.041**	**0.034**	**0.028**
Medium to Coarse*	0.211	0.156	0.115	0.082	0.058	0.044	0.035	0.029	0.021	0.016	0.013
Coarse to Very Coarse*	0.183	0.124	0.082	0.053	0.037	0.028	0.022	0.018	0.013	0.010	0.008
Very Fine to Fine*	0.373	0.340	0.305	0.262	0.226	0.197	0.175	0.155	0.127	0.108	0.095
AT401, M, 10 mph, 34% SD	0.234	0.183	0.142	0.105	0.078	0.060	0.049	0.042	0.032	0.026	0.021
WASP, M, 10 mph, 34% SD	0.218	0.171	0.129	0.086	0.063	0.049	0.040	0.034	0.026	0.021	0.018
AT401, C, 10 mph, 25% SD	0.198	0.141	0.099	0.067	0.047	0.036	0.029	0.024	0.017	0.013	0.011
WASP, C, 10 mph, 25% SD	0.171	0.121	0.084	0.053	0.038	0.028	0.023	0.018	0.013	0.010	0.009
AT401, VC, 10 mph, 20% SD	0.175	0.115	0.072	0.044	0.031	0.023	0.018	0.014	0.010	0.008	0.006

Table B-1. Average Drift Fractions for a 50' Wide Lawn Starting at Various Distances Downwind from a Field Treated Using Aerial Equipment.

Droplet Size+	Distance Downwind from Treated Field (feet)										
	0	10	25	50	75	100	125	150	200	250	300
WASP, VC, 10 mph, 20% SD	0.138	0.088	0.057	0.036	0.025	0.019	0.014	0.012	0.008	f.007	0.006

*Information is based on the Tier 1 option in the AgDrift model. The fine to medium spray quality is used in this SOP as the basis for the screening level assessment. These are all based on fixed wing aircraft.
+For further options the AT401 is the representative fixed wing aircraft and the Wasp is the representative helicopter. SD = swath displacement. SD values for non-Tier I options computed using AgDrift automated adjustment option.

Spray Quality Summaries: Fine to Medium (F2M): $D_{v0.5}$ = 255 µM; Medium (M): $D_{v0.5}$ = 294 µM; Medium to Coarse (M2C): $D_{v0.5}$ = 341 µM; Coarse (C) $D_{v0.5}$ = 385 µM; Coarse to Very Coarse (C2VC): $D_{v0.5}$ = 439 µM;

Table B-2. Average Drift Fractions for a 50' Wide Lawn Starting at Various Distances Downwind from a Field Treated Using Ground Equipment.

Boom Height	Droplet Size	Distance Downwind from Treated Field (feet)										
		0	10	25	50	75	100	125	150	200	250	300
High	***Very Fine to Fine***	**0.187**	**0.093**	**0.056**	**0.035**	**0.025**	**0.020**	**0.017**	**0.014**	**0.011**	**0.008**	**0.007**
Low	Very Fine to Fine	0.085	0.032	0.020	0.013	0.010	0.008	0.007	0.006	0.005	0.004	0.003
High	Fine to Medium/Coarse	0.049	0.019	0.013	0.009	0.007	0.006	0.005	0.005	0.004	0.003	0.003
Low	Fine to Medium/Coarse	0.033	0.012	0.008	0.006	0.005	0.004	0.003	0.003	0.002	0.002	0.002

Low Boom 0.508 m (20 in), High Boom 1.27 m (50 in)
Fine to Medium/Coarse (F2M/C): Avg. Droplet size ($D_{v0.5}$) = 341 µM

Post-application Hand-to-Mouth Exposure Algorithm—Physical Activities on Turf

Exposure from hand-to-mouth activity is calculated as follows (based on the algorithm utilized in the SHEDS-Multimedia model):

$$E = [HR * (F_M * SA_H) * (ET * N\_Replen) * (1- (1- SE)^{(Freq\_HtM/N-Replen)})]$$

where:

E	=	exposure (mg/day);
HR	=	hand residue loading (mg/cm^2);
FM	=	fraction hand surface area mouthed / event (fraction/event);
SAH	=	typical surface area of one hand (cm^2);
ET	=	exposure time (hr/day);
N_Replen	=	number of replenishment intervals per hour (intervals/hour);
SE	=	saliva extraction factor (i.e., mouthing removal efficiency); and
Freq_HtM	=	number of hand-to-mouth contact events per hour (events/hour).

and

$$HR = \frac{Fai_{hands} * DE}{SA_H * 2}$$

where:

HR	=	hand residue loading (mg/cm^2);
Fai_{hands}	=	fraction ai on hands compared to total surface residue from dermal transfer coefficient study (unitless);
DE	=	dermal exposure (mg); and
SA_H	=	typical surface area of one hand (cm^2).

Dose, normalized to body weight, is calculated as:

$$D = \frac{E}{BW}$$

where:

D	= dose (mg/kg-day);
E	= exposure (mg/day); and
BW	= body weight (kg).

Table B-3. Turf (Physical Activities) – Inputs for Residential Post-application Hand-to-Mouth Exposure			
Algorithm Notation	**Exposure Factor (units)**		**Point Estimate(s)**
Fai_{hands}	Fraction of ai on hands from dermal transfer coefficient study (unitless)	Liquid formulations	0.06
		Granular formulations	0.027
DE	Dermal exposure (mg)		Calculated
SA_H	Typical surface area of one hand (cm^2), children 1 < 2 years old		150
AR	Application rate (mass active ingredient per unit area)		0.5
HR	Residue available on the hands (mg/cm^2)		Calculated via (DE * Fai_{hands})/SA_H
F_M	Fraction hand surface area mouthed (fraction/event)		0.127
N_Replen	Replenishment intervals per hour (intervals/hr)		4
ET	Exposure time (hrs/day)		1.5
SE	Saliva extraction factor (unitless)		0.48
Freq_HtM	Hand-to-mouth events per hour (events/hr)		13.9
BW	Body Weight (kg)	Children 1 < 2 years old	11

Table B4. Children's (1 to <2 Years Old) Risk Estimates (MOEs) Related to Indirect Hand to Mouth for Propanil Exposure.														
Crop/Rate Group	**Spray Type/ Nozzle Configuration**	**Appl. Rate (lb ai/A)**	**TTR_t[a] (ug/cm2)**	**At Edge**	**10 Feet**	**25 Feet**	**50 Feet**	**75 Feet**	**100 Feet**	**125 Feet**	**150 Feet**	**200 Feet**	**250 Feet**	**300 Feet**
Rice														
Aerial	***Fine to Medium***	6	0.6669	383	471	583	764	1005	1296	1564	1824	2403	2897	3518
	Medium to Coarse			467	631	857	1201	1698	2239	2814	3397	4691	6156	7577
	Coarse to Very Coarse			538	794	1201	1859	2662	3518	4477	5472	7577	9850	12313
	Very Fine to Fine			264	290	323	376	436	500	563	636	776	912	1037
	AT401, M, 10 mph, 37% SD			421	538	694	938	1263	1642	2010	2345	3078	3789	4691
	WASP, M, 10 mph, 37% SD			452	576	764	1145	1564	2010	2463	2897	3789	4691	5472
	AT401, C, 10 mph, 25% SD			497	699	995	1470	2096	2736	3397	4104	5794	7577	8955
	WASP, C, 10 mph, 25% SD			576	814	1173	1859	2592	3518	4283	5472	7577	9850	10945
	AT401, VC, 10 mph, 20% SD			563	857	1368	2239	3178	4283	5472	7036	9850	12313	16417
	WASP, VC, 10 mph, 20% SD			714	1119	1728	2736	3940	5184	7036	8209	12313	14072	16417
Rice														
Groundboom	***High Boom Very fine to Fine***	6	0.6669	527	1059	1759	2814	3940	4925	5794	7036	8955	12313	14072
	Low Boom Very fine to Fine			1159	3078	4925	7577	9850	12313	14072	16417	19701	24626	32834
	High Boom Fine to Medium/Coarse			2010	5184	7577	10945	14072	16417	19701	19701	24626	32834	32834
	Low Boom Fine to Medium/Coarse			2985	8209	12313	16417	19701	24626	32834	32834	49252	49252	49252